Group Art Unit: 1645 Attorney Docket No.: UIZ-003DVCNCPA Examiner: Swartz, Rodney P.

REMARKS

Claims 44-79 were pending in the instant application. Claims 44, 45, 54, 75, and 76 have been amended. Claims 71-73 have been cancelled. Claims 46-53 and 77-79 have been withdrawn from consideration by the Examiner. Accordingly, claims 44-45, 54-70, and 74-76 will be pending in the application upon entry of the instant amendment. No new matter has been added.

Independent claims 44 and 45 have been amended to more particularly point out and distinctly claim the subject matter that the Applicants regard as the invention. Support for the amendment of the claims can be found throughout the specification and claims as previously presented. In particular, support for the amendment of claims 44 and 45 may be found in the specification, at least for example, on page 6, lines 20-24, and on page 9, lines 3-13. Additionally, claims 71-73 were cancelled, and dependent claims 75-76 were amended, reflecting the amendment to the independent claims.

Claims 54 has been amended to more particularly point out and distinctly claim the subject matter that the Applicants regard as the invention. Support for the amendment of the claims can be found throughout the specification.

Amendment and/or cancellation of the claims is not to be construed as acquiescence to any of the objections/rejections set forth in the instant Office Action or any previous Office Action, and were done solely to expedite prosecution of the application. Applicants reserve the right to pursue the claims as originally filed, or similar claims, in this or one or more subsequent patent applications.

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Response to Restriction Requirement

Restriction Requirement of December 13, 2002

In the Office Action of December 13, 2002 (on page 2), the Applicants were restricted to one of the following groups under 35 U.S.C. §121:

Claims 44-74 drawn to a method of selecting inhibitors of an autoinducer Group I:

classified in class 514 subclass 438 and 461;

Claims 44-73 and 75 drawn to a method of selecting inhibitors of an Group II:

autoinducer classified in class 514 subclass 438 and 461;

Group III: Claims 44-73 and 76 drawn to a method of selecting inhibitors of an

autoinducer classified in class 514 subclass 438 and 461;

Group IV: Claims 77-79 drawn to an inhibitor classified in class 540.

Applicants respectfully traversed the requirement for restriction to one of the abovereferenced groups in Applicants' response of January 13, 2003 (which is hereby incorporated by reference in its entirety, and the Examiner is respectfully requested to refer to the arguments contained therein), submitting the restriction was improper. Applicants further outlined that all of the claims are linked by a single, searchable, unifying aspect; i.e., autoinducer molecules of Pseudomonas aeruginosa.

Applicants further submit that Groups I, II, III are all subgeneric positions relative to the method of claim 44, which method includes the step of "measuring the ability of the treated autoinducer molecule to stimulate the activity of a selected gene," and thus a search of claim 44 would, at a minimum, encompass the claims of Groups I, II, and III. Applicants therefore submit that a sufficient search and examination with respect to the subject matter of all claims can be made without serious burden in accordance with M.P.E.P. § 803, even, assuming arguendo that the above-enumerated groups of claims are drawn to distinct inventions. Applicants submit that

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the search and examination of all the claims will have substantial overlap, and no serious burden will result from searching and examining all claims in the same application. This is especially true inasmuch as Groups I-III, as shown above, have *exactly the same classification*; *i.e.*, class 438, subclass 461. At a minimum, Applicants request that Groups I-III be rejoined into a single group.

Nevertheless, in compliance with the directives in the Office Action and in order to expedite prosecution of the instant application, Applicants elected, subject to traverse, Group I, claims 44-74 drawn to a method of selecting inhibitors of an autoinducer classified in class 514 subclass 438 and 461.

Restriction Requirement of October 2, 2003

While Applicants, through its agent, have provisionally elected Group I of this most recent restriction requirement, Applicants take this opportunity to respectfully point out that the merits of Applicants prior response of January 13, 2003, have not been addressed, *nor has the response even been acknowledged on the record*.

Moreover, no amendment to the claims was requested in Applicants' response of January 13, 2003 that would have necessitated the issuance of a subsequent restriction requirement by the Examiner. Accordingly, Applicants find it improper for such a requirement to issue, particularly, that such a response should issue without withdrawal of the previous restriction requirement or a provision of an explanation of why such withdrawal would be necessary in the absence of necessitating amendments. However, in order to be responsive to the requirement for restriction, Applicants hereby elect Group I subject to the foregoing traverse.

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Specification

The specification has been objected to based on the informalities listed in the Office Action on page 5. Applicants have amended the specification to correct these typographical errors, and therefore respectfully request withdrawal of this objection.

Priority Statement

The Office Action on page 5 has requested an update of the status of all priority documents. Applicants have amended the specification on page 1, to update the status of these priority documents, and therefore respectfully request withdrawal of this objection.

Claim Rejections

Rejection of Claims 44, 45, and 54-76 under 35 U.S.C. §112, Second Paragraph

Claims 44, 45, and 54-76 are rejected under 35 U.S.C. §112, second paragraph, as failing to point out and distinctly claim the subject matter that the Applicants regard as the invention. In particular, on page 5 and 6, the Office Action asserts that "[i]t is unclear from the claim language how many autoinducers are being claimed," and recommends that "... the language be consistent throughout the claims."

Claim 45 has been amended to recite "an" autoinducer molecule. Support for the amendment of this claim can be found throughout the specification. Accordingly, Applicants respectfully request withdrawal of the rejection and favorable reconsideration.

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Claims 65-70 are rejected under 35 U.S.C. §112, second paragraph, as failing to point out and distinctly claim the subject matter that the Applicants regard as the invention. In particular, on page 6, the Office Action asserts that "[i]t is unclear to which molecule in claim 54 that claims 65-70 are referring, i.e., the autoinducer molecule or the molecule which the autoinducer comprises."

Claims 54 has been amended to recite "a compound of formula I:". This amendment clarifies the language of claim 65-70. Support for the amendment of this claim can be found throughout the specification. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 65-70 under 35 U.S.C. §112, second paragraph.

Claims 74-76 are rejected under 35 U.S.C. §112, second paragraph, as indefinite. In particular, on page 6, the Office Action asserts that "[t]he use of 'E. coli MG4' as the sole means of identifying . . . a bacteria which contains plasmid pKDT17 renders claims 74-76 indefinite because 'E. coli MG4' is merely a laboratory designation which does not clearly define the product since different laboratories may use the same laboratory designation to define completely distinct strains of E. coli."

Applicants respectfully traverse this rejection. Applicants submit that one skilled ion the art would not find the designation confusing, especially in light of the instant specification. In this regard, Applicants respectfully invite the Examiner's attention to page 14, lines 23-28 of the specification, where the E. coli strains, e.g., MG4, is defined according to the specific journal articles recited:

> The E. coli strains used were TBI (Gibco-Bethesda Research Laboratories Life Technologies (1984) Focus 6, 4), MG4 (Railing, G., Bodrug, S. and Linn, T. (1985) Mol. Gen. Genet. 201, 379-386), and VJS533 (Stewart, V. J. and Paroles, J.V., Jr. (1988) J. Bacteriol. 170, 1589-1597). (Emphasis Added)

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Thus, assuming *arguendo* that one of ordinary skill in the art would find the designation confusing, they would have access to the recited articles which describe the strains of *E. coli* strain used in the experimentation, *e.g.*, MG4, thereby providing a clear indication as to which particular strain is included within claims 74-76. Applicants, therefore, submit that claims 74-76 are not indefinite, and request withdrawal of the rejection of claims 74-76 under 35 U.S.C. §112, second paragraph.

Rejection of Claims 44, 45, and 54-58, and 60-76 under 35 U.S.C. §112, First Paragraph

Claims 44, 45, 54-58, and 60-76 are rejected under 35 U.S.C. §112, first paragraph. In particular, the Office Action, on page 6, suggests that "the specification, while being enabled for methods of selecting inhibitors or synergists of the specific autoinducer N-(3-oxododecanoyl)homoserine lactone of *P. aeruginosa*, does not reasonably provide enablement for methods of selecting inhibitors or synergists of any/all other autoinducers of *P. aeruginosa*."

Applicants respectfully traverse this rejection. Applicants submit that the claims, as amended, are not directed to "methods for selecting inhibitors or synergists of <u>any/all</u> autoinducers of *P. aeruginosa*," as suggested by the Office Action; but rather the claims are directed to methods for selecting inhibitors or synergists of autoinducers that *regulate the* activity of the LasR protein of *P. aeruginosa*. Support for the amendment of claims 44 and 45 may be found in the specification, at least for example, page 6, lines 20-24, and on page 9, lines 3-13. Additionally, claims 71-73 were cancelled and dependent claims 75-76 were amended, reflecting the amendment to claim 44.

Furthermore, the specification provides a sufficient number of examples of how to make and use autoinducer molecules that comprise several genus molecules, including the formulae described at least on page 2 and the description of "analogs" contemplated within the present invention on page 8, lines 8-20, as well as several species, such as N-(3-oxododecanoyl)homoserine lactone. In addition, Applicants have provided autoinducer

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bioassays, at least for example on page 16-17 of the specification, that provide the ordinarily skilled artisan direction on how to use the present invention, e.g., how measurement of the ability of the treated autoinducer molecule to stimulate the activity of LasR_may be made.

As such, Applicants submit that amended independent claims 44 and 45 are clearly enabled by the present application. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 44, 45, 54-58, and 60-76 under 35 U.S.C. §112, first paragraph.

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CONCLUSION

In view of the foregoing remarks presented, favorable reconsideration and withdrawal of the rejections, and allowance of this application with all pending claims are respectfully requested. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is invited to call the undersigned at (617) 227-7400.

Respectfully submitted,

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